Cat. No. 65N50000

Baxter

Pharmaseal®

RK-2000 Hypo/Hyperthermia Unit

Operation and Service Manual

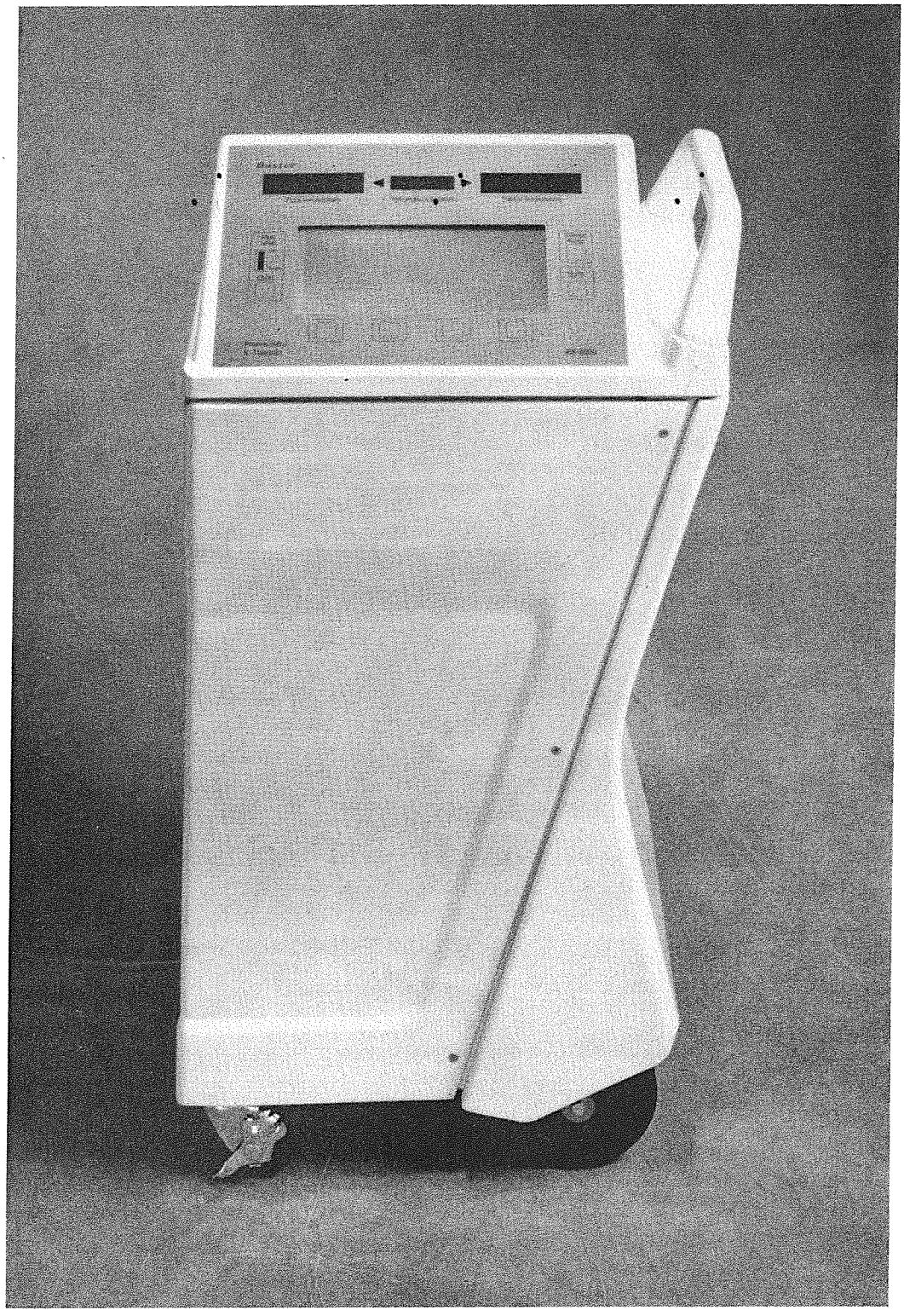

Table of Contents

Page

Section 1 – Introduction

Warranty 1
Product Description 1
Control Panel 2
Interface Panel 2
General 2
Figure 1 3
Figure 2 4

Product Specifications:

Physical 5
Control System 5
Thermal System 5
Circulating System 5
Electrical System 5
Performance Characteristics 5
Safety Systems 5
Alarms 5
Warnings 6

Section 2 – Equipment Operation

Preparation For Use 7
Modes of Operation 7
Operation 7-8
Operating Instructions 8
Alarms and Messages 9
Status Messages 9
Alarms and Warnings (Troubleshooting) 9
Cleanup 10

Section 3 – Service and Repair

Service Mode 11
Panel 11
Output 11-12
Temp 12

Page

Status 12
Preventive Maintenance 12-16
Figure 3 14
Repair 16-18
Figure A 19
Figure B 20
Figure C 21
Figure D 22
Figure E 23
Figure F 24
Troubleshooting 25
Low Fluid Flow 25
Patient Probe Fault 25
System Malfunction 25-26
Secondary Heat Limit Activation 26
Theory of Operation 26-27
Thermal System 26
Circulating System 27
Electrical System 27-29

Section 4 – Parts List Information

Catalog No. 30
Description 30
Figure No. 30
Service Parts Warranty 30
Parts List 31
Accessory Sales Information 32

Section 5 – Schematics

Main Control Board 34-35
LED Display 36
Patient Monitor 37
Power Module 38

Section 1 – Introduction

Warranty: This product is warranted by Baxter Healthcare Corporation, Pharmaseal Division, to be free from defects in workmanship and materials under normal use for a period of twenty-four (24) months from the date of sale or twenty-seven (27) months from the date of manufacture, whichever occurs first.

Service parts listed in this manual are warranted to be free from defects in workmanship and materials, under normal use and service, for a period of ninety (90) days from the date of shipment.

This warranty is expressly in lieu of any other express or implied warranties including any implied warranty of merchantability of fitness for purpose and of any other obligation on the part of Baxter Healthcare Corporation, Pharmaseal Division.

The purpose of this manual is to provide the operator and the biomedical equipment technician with proper operating and technical information for the RK-2000.

Repair of the RK-2000 should be done by a person who has basic knowledge of electronics, hydraulics and experience in servicing medical equipment. The technical information contained in this manual should be used as a guide for preventive maintenance and parts replacement.

Baxter's Pharmaseal Division welcomes suggestions for improvements to our equipment. If assistance is needed in solving an operation or technical problem, contact:

Baxter Healthcare Corporation
Product Service Management Division
750B Tower Road
Mundelein, IL 60060

or call our Technical Service Department at:
~~1-800-323-9098~~
GAYMAR Industries
800/828-7341

1.1 Description of RK-2000:

The RK-2000 Hypo/Hyperthermia Unit is a device used to assist the attending medical staff in influencing or maintaining a patient's body temperature. This machine is a portable hot or cold water circulating device which transfers thermal therapy to the patient via a warming/cooling blanket. Thermal transfer is accomplished by surface heat transfer from the circulating blanket to the patient. The machine has connections for two blankets, making it possible to have blankets both over and under the patient simultaneously.

The RK-2000 is designed for simple setup, operation and service. The large screen display in the center of the control panel guides the user step-by-step through the setup procedure. This same screen informs the user of the status of the equipment and during abnormal conditions, displays information regarding the equipment fault and corrective actions to be taken. The modular construction of the equipment allows for ease of service. The smooth surface and minimum number of seams facilitate easy cleaning.

The following is a description of the main features of the RK-2000. The numbers refer to the location of each feature in **Figures 1** and **2**:

1.2 Control Panel:

(1) **Fluid Temperature Display.** A digital display presents the temperature of the circulating fluid.

(2) **Patient Temperature Display.** A digital display presents the patient temperature. This display only functions when the patient is properly connected to the machine via a 400 series patient temperature probe.

(3) **Setpoint Temperature.** A digital display presents the setpoint temperature. This display reflects the desired setpoint for fluid temperature when in the heat or cool mode, or the desired setpoint for the patient temperature when in the automatic mode.

(4) **Mode Indicator Arrows.** These arrows indicate which mode is controlling the setpoint temperature. When the left arrow is illuminated, it indicates that the fluid temperature is the setpoint. This is referred to as **manual** mode. If the right arrow is illuminated, it indicates that the patient temperature is the setpoint. This is the **automatic** mode of operation.

(5) **Fluid Level Indicator and Check Switch.** This indicator displays the quantity of fluid in the reservoir. By pressing the **check** button, the appropriate digital bar will light to show fluid level. This is a battery operated system and will operate whether or not the machine is connected to a power supply. During normal operation the display will be lit continuously.

(6) **Silence Alarm.** This switch, when pressed while the alarm is sounding, will silence the alarm for two minutes. There is no limit to the number of times the silence alarm switch can be pressed.

(7) **°C/°F.** This switch, when pressed, changes all temperature displays alternately between degrees Centigrade and Fahrenheit.

(8) **Main Graphics Display.** This display shows the setup menus, patient trend graph, machine status, warnings and error conditions.

(9) **Soft Key Switches.** The four switches at the bottom of the main graphics display are used to set up the equipment for operation or to change conditions during operation. Their functions are assigned for each menu and are displayed on the Main Graphics Display.

1.3 Interface Panel:

(10) **Main Power Switch.** This switch controls electrical power to the RK-2000. Turning the switch **off** will erase all setup conditions previously programmed.

(11) **Blanket Connection.** These connectors are for attaching the fluid hoses to the machine. The hoses connect to the patient blanket. There are four ports, two inlets and two outlets, for connecting one or two patient blankets.

(12) **Patient Monitor.** This ¼", 2-wire phone jack permits connecting a 400 series patient temperature probe to the machine. An approved extension cable (⅛" jack to a ¼" phone plug) must be used. For patient safety, this connection is electrically isolated from the rest of the machine.

1.4 General:

(13) **Handle.** Transport handle for the machine.

(14) **Fill Port.** Location for filling the reservoir. Use distilled water only.

(15) **Fill Port Cover.** Cover for fill port. This is attached to the equipment with a stainless steel chain.

(16) **Blanket Storage Slot.** Area for storing new disposable blanket, probe and connector tubing.

(17) **Wheels.** The front wheels are lockable casters. The rear wheels are unidirectional.

(18) **Power Cord.** The AC power cord terminates in a hospital-grade 115 volt grounding plug. Use only hospital grade outlets to ensure proper grounding of the equipment.

1.5 Product Specifications of RK-2000:

Physical:

Length: 19″.....48.3cm
Depth: 15.5″.....39.4cm
Height: 37.25″.....94.6cm
Weight: 130 lbs.....59kg
Construction: Welded steel frame with ABS housing

Control System:

Controller Range:
- Water temperature: 5-42°C (41-107.6°F)
- Patient temperature: 30-38°C (86-100.4°F)

Fluid Temperature Accuracy:
- Water temperature monitor: ±0.5°C (±0.9°F)
- Water temperature control: ±2.0°C (±3.6°F)

Display Range:
- Water temperature: 0.0-50.0°C (32-122°F)
- Patient temperature: 27.0-42.0°C (80.6-107.6°F)

Display Type:
- LED fluid, patient and setpoint temperature displays.
- LCD Graphics display (640 x 200 pixels) for setup, warnings, system status and patient temperature trend graph.

Modes of Operation:
- Heat
- Cool
- Automatic
- Monitor
- Service (for service personnel use only)

Patient Monitor:
- Measurement accuracy: ±0.25°C (±0.45°F)
- Probe type: 400 series thermistor
- Number of connections: One
- Display resolution: 0.1°C (0.18°F)

Thermal System:

Compressor:
- Power rating: ⅓ hp
- Refrigerant: Freon 12
- Charge capacity: 12.5 oz
- Evaporator test pressure: High side 500 psi, Low side 250 psi

Heater:
- Power rating: 800 watt
- Heater type: Dry bore, cartridge

Circulating System:

- Fluid: Distilled water
- Internal capacity: Two gal
- Quick connect/disconnect couplings
- Connection ports for two blankets
- Two stage water filter
- Internal water safety bypass
- Battery backed up water level indicator

Electrical System:

Power requirements: 115V, 9.5 amps, 60 hz
Power cord: 14/3 SJTO 15′ long, hospital grade plug, 15 amp rating (NEMA 15-5P)
Leakage current: Less than 100 microamps
Circuit breaker: In power switch

Performance Characteristics:

Fluid circulating rate: Approximately 18 GPH through a 60″ x 24″ Duo-Therm® Blanket
Approximately 36 GPH unrestricted
Cooling rate at 24°C (75.2°F) ambient temperature: 2.2°C (3.96°F)/minute when attached to a 60″ x 24″ Duo-Therm Blanket
Heating rate at 24°C (75.2°F) ambient temperature: 2.8°C (5°F)/minute when attached to a 60″ x 24″ Duo-Therm Blanket

Safety Systems:

Maximum control setting: 42°C (107.6°F)
Primary independent backup: 45.0±2.7°C (113±4.9°F) auto reset
Secondary independent backup: 47.2±4.4°C (116.9±7.9°F) manual reset
Minimum control setting: 5°C (41°F)
Minimum independent backup: 2.2±1.7°C (35.9±3°F)

Alarms:

Defective, dislodged, or out-of-range patient probe	Audible and Visual
Primary high and low temperature limits activiated	Audible and Visual
Secondary heat limit activated	Audible
Low water warning	Audible and Visual
Empty reservoir	Audible and Visual
Full reservoir	Audible and Visual
Defective control thermistor	Audible and Visual
Low water flow	Audible and Visual
Heater/cooler failure	Audible and Visual
Microprocessor failure	Audible and Visual
Water level sensor malfunction	Audible and Visual

Warnings:
This equipment is to be used under the supervision of qualified medical personnel only.

Select setpoint temperature carefully. When using this device, it is important to check the patient's skin condition often. Due to variation in skin sensitivity, some patients are more susceptible to skin damage from externally applied chemicals, pressure and temperature. Patients particularly susceptible are those under prolonged therapy, children, diabetics, incapacitated patients and those with insensitive skin areas, or where poor circulation is present.

Danger: Possible explosion hazard if used in the presence of flammable anesthetics.

Warning: The use of an electrosurgical/cautery unit requires assurance of adequate generator performance and grounding with proper placement and integrity of patient grounding pads. Improper and/or inadequate grounding of the electrosurgical unit and/or patient increases the probability of any electrical device or temperature sensor/probe serving as a path to ground for any spurious RF current, and could possibly result in a burn to the patient.

Caution: The potential of interference on all hypo/hyperthermia units from electrosurgical/cautery units (ESU) increases when a hypo/hyperthermia machine is plugged into the same duplex electrical outlet as an ESU. Interference is also possible if the ESU leads are in close proximity to electrical leads of the hypo/hyperthermia unit. For best performance, plug the ESU into a separate outlet as far away as possible from the hypo/hyperthermia unit. Also maintain as much distance as possible between the ESU unit and leads and the hypo/hyperthermia unit and leads.

If there is any doubt regarding the proper operation or adequate grounding of the generator or adequate grounding of the patient, all electrical devices and temperature sensors/probes should be disconnected.

Section 2 – Equipment Operation

2.1 Preparation for Use:

The following instructions are the recommended procedure for preparing the equipment for use. Several steps are good user practice from a safety standpoint and should become routine.

1. Inspect the unit for signs of damage, specifically the power cord and plug. If damaged, return the equipment to Biomedical Engineering for repair.
2. Press the fluid level **check** button to determine fluid level in the machine. If the fluid level is less than ¾ full, refill the unit.
3. If more fluid is required, remove the fill port cover located on the handle side on the top of the unit. Add distilled water to the fill port, frequently checking fluid level as described in step two. Stop filling when the water level shows the unit to be full. (If the machine is powered **on**, an alarm will sound when the unit is full.)
4. Move unit into position and attach power cord to a grounded, hospital-approved power outlet (15 amp rating).
5. Place a Duo-Therm® Blanket on the operating table or bed. Connect the extension tube to the machine at the point under the handle labeled **connect pad**. Be sure to attach one connector to the inlet and one to the outlet. Connect the other end of the extension tube to the Duo-Therm Blanket. Snap the connectors securely together to prevent leakage. Place the patient on the blanket or under the blanket. A second blanket may be placed over/under the patient to increase the thermal transfer to the patient. Re-check the blanket and extension hose for kinks or folds.
6. If the patient's temperature is to be monitored, the patient temperature probe must be connected. Connect the 10′ probe extension cable to the **patient monitor** jack on the RK-2000 (located under the handle). The other end of the extension cable is then connected to a 400 series thermistor patient temperature probe. This probe should be attached to the patient per the instructions on the probe package.

The RK-2000 is now ready to operate.

2.2 Operation:

Read the "Warnings" section before operating the RK-2000.

Modes of Operation:

There are four modes of operation with the RK-2000:

1. **Heat Mode.** This mode of operation allows the operator to circulate heated water at a selected fluid temperature. The operator selects the desired fluid temperature setpoint. The machine will then control the water temperature to that setpoint. This mode also allows the user to monitor patient temperature without having the patient's temperature affect the machine's operation.
2. **Cool Mode.** This mode of operation allows the operator to circulate chilled water at a selected fluid temperature. The operator selects the desired fluid temperature setpoint. The machine will control the water temperature to that setpoint. This mode also allows the user to monitor patient temperature without having the patient's temperature affect the machine's operation.
3. **Automatic Mode.** This mode of operation allows the operator to select a desired **patient** temperature. The machine will then automatically adjust the water temperature to influence the patient's temperature toward the setpoint within the 30-38°C (86-100.4°F) range. In this mode the patient temperature probe is a critical element of the operating system. If disconnected or sensing a temperature not in the operating range of 27-42°C (80.6-107.6°F), the unit will alarm and thermal control will cease until the probe is reconnected.
4. **Monitor Mode.** This mode of operation is for monitoring the patient's temperature only. There is no thermal transfer when operating in this mode. For the patient's temperature to be displayed, the patient temperature probe must be connected. If it is not connected, the unit will not alarm. Instead, it will display a message that requests the operator to connect the probe. Additionally, screen brightness is controlled in this mode.

Operating Instructions:

1. **Power On.** Turn the RK-2000 **on** with the **power** switch located under the handle. The unit will undergo an automatic pre-check. At this time the message **please wait** will be displayed on the graphics screen. When the self-test is successfully completed, the unit will display the **select desired mode** screen.
2. **Select Mode of Operation:**
   Note: If an error is made in setting up the equipment, the operator can return to the select desired mode menu by pressing **change mode**.
   To activate the Heat Mode. Press the **heat** soft key switch. The **select temperature setpoint** screen will then appear. Select the desired fluid temperature setpoint by using the up or down arrows. When the desired fluid temperature setpoint is displayed, press **start**. The unit will now control the circulating fluid temperature to the desired setpoint.

   To activate the Cool Mode. Press the **cool** soft key switch. The **select temperature setpoint** screen will then appear. Select the desired fluid temperature setpoint by using the up or down arrows. When the desired fluid temperature setpoint is displayed, press **start**. The unit will now control the circulating fluid temperature to the desired setpoint.

   To activate the Automatic Mode. Ensure that the patient temperature probe is connected to the patient monitor jack located on the right side of the unit. If the probe is not connected or if it is sensing a temperature not in the operating range of 27-42°C (81-107.6°F), the automatic mode will not activate and an alarm will sound. For probe connection instructions, see **Preparation For Use**, No. 6. Press the **automatic** soft key switch. The **patient temperature setpoint** screen will then appear. Select the desired patient temperature by using the up and down arrows. When the desired patient setpoint temperature is displayed, press **start**. The unit will now control the circulating fluid temperature so as to influence the patient's body temperature toward the selected patient temperature setpoint.

   To activate the Monitor Mode. Press the **monitor only** soft key switch. The patient temperature trend graph will then appear and begin charting the patient's temperature. If a patient temperature probe is not in place, the graphics screen will prompt the user to install a patient probe. In the monitor mode there is no heating or cooling of the fluid. Brightness of the screen is also controlled in this mode. Press the **screen bright** soft key switch several times and the backlighting will step down in intensity and then return to the maximum level of brightness.
3. **Operating Screen and Alternatives:**
   Once the RK-2000 is operating, the main graphics display will display either the patient temperature trend graph, or a note to connect the patient temperature probe if a patient trend graph is desired.

   If the patient temperature trend graph is displayed, there are three choices to modify operation of the equipment. The three choices are:

   Change Mode. This will return the user to the select mode screen, allowing the selection of another mode of operation or a different setpoint temperature in the same mode of operation.

   Pause. This will put the equipment into a standby state. The circulating pump will shut **off** five seconds after pressing **pause** and the heater or cooler will be deactivated. (**Note:** If the unit is placed in **pause** from the **cool** mode, the compressor will continue to operate, but the cooling control will be turned **off**. See **Theory of Operation**.)

   From the **pause** condition, there are two choices of action: **Change mode** will return the user to the selection menu for a change of operating conditions. **Resume** will return the user to full operation with the same setpoint conditions and operating mode that existed before entering the **pause** condition.

   Reset Trend. This will allow the user to clear the Patient Trend Graph currently displayed on the screen. There is a safety feature built into the command to prevent accidental loss of patient temperature trend data. Once **reset trend** has been pressed, the options of **old chart** or **new chart** are given. Selecting **old chart** will return to the current chart without losing any of the temperature data. Selecting **new chart** will clear all existing data and start a new chart. This will erase all current patient trend data.

   If the patient trend graph is not displayed, a note will appear to connect a patient temperature probe if a patient trend graph is desired. If this message is displayed, the following will result in the four operating modes:

   In the **automatic** mode, an alarm will sound and a **patient probe fault** message is displayed. This mode controls to a patient temperature and cannot operate without a patient probe in place.

   In the **monitor** mode, the **change mode** option is available as described above. No patient temperature will be displayed without the probe in place. A **screen bright** option is also available and will change the brightness of the screen backlighting as described above.

   The **heat** and **cool** modes will operate properly with this note displayed. The two options available are **change mode** and **pause**. These are the same as described above.

2.3 Alarms and Messages:

The following are messages and alarms which will be displayed on the graphics screen to indicate trouble conditions or to advise the user of certain status conditions of the equipment.

Status Messages	
To Monitor Patient Temperature, Connect 400 Series Probe	This message indicates that a patient temperature probe is not connected to the equipment. It will be displayed on the graphics screen in the heat or cool mode of operation but it will not affect operation of the equipment.
Please Wait	This screen indicates that the equipment is undergoing self-test. It will only be displayed when the machine is first turned on.
Reservoir Full	This message is displayed when the reservoir reaches the full level. A short audible alarm sounds along with this message. This message will clear from the screen within 10 seconds.
Alarms and Warnings (Troubleshooting)	
Low Fluid Flow	This alarm message warns of a low fluid flow condition with the equipment (below 6 GPH). Follow the troubleshooting steps on the screen to resolve the problem. Once the problem is resolved, the message will be cleared from the screen and the unit will return to normal operation.
High Temp Limit	This message will appear whenever the high temperature limit switch is activated. While this message is displayed, the heater will be deactivated. The fluid, however, will continue to circulate. This switch will automatically reset when the temperature drops 5-7°C (9-13°F). This clears the message from the screen and the equipment returns to normal operation.
Secondary High Temp Limit	This limit is a back-up for the high temperature limit. When this limit is activated, a buzzer will sound. The unit must be turned **off** to stop the buzzer, then removed from service and sent to the proper repair facility (Biomedical Engineering).
Low Temp Limit	This message will appear whenever the low temperature limit switch is activated. While this message is displayed, cooling will be deactivated. The fluid, however, will continue to circulate. This switch will automatically reset when the temperature raises 5-7°C (9-13°F). This clears the screen and returns the equipment to normal operation.
Patient Probe Fault	This message indicates that the patient temperature probe is not properly connected to the machine or is sensing a temperature not in the operating range of 27-42°C (80.6-107.6°F). This could be due to the probe not being properly attached to the patient. This message will only appear in the automatic mode where the patient probe is a required element. While this message is displayed, all thermal controls will be suspended. The fluid, however, will continue to circulate.
Warning Low Fluid Level	This message is displayed when the fluid level in the reservoir is low. The machine will still operate, and pressing **clear screen** will return the display to the previous screen. When this warning is displayed, it is recommended to refill the machine as soon as possible.
Reservoir Empty	This message is displayed when the fluid level in the reservoir has dropped below a safe operating level. The pump will stop circulating and there will be no thermal control until the reservoir is refilled, at which time the unit will resume operation.
System Malfunction Remove from Service Return to Biomed.	This message appears when a fault has occurred with the equipment that is not user serviceable. Remove the unit from service and send it to a qualified service facility (Biomedical Engineering).

2.4 Cleanup:

To remove the unit from service, use the following steps:

1. Turn **off** unit power.
2. Disconnect the disposable patient temperature probe, if used, from the temperature probe extension cable. Discard the disposable temperature probe.
3. Disconnect the disposable blanket from the extension hose by closing the clamps tightly and depressing the thumb tab on the quick disconnects. Discard the disposable blanket.
4. Disconnect the power cord from the wall and loop the cord and extension hose. Attach the hose and power cord to the unit using the strap at the rear of the unit.
5. Clean the unit with a 1:10 dilution of household bleach and water. The unit is spill proof, so ample quantities of cleaner can be used without damage to the equipment. Wipe down the unit with clean water and dry with a cotton towel. Exercise caution when cleaning the control panel so as not to scratch the surface. Avoid the use of hydrocarbon based cleaners as these will damage the plastic housing.
6. It is recommended that the unit be drained for prolonged storage. (See **Preventive Maintenance**.)